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13. SUPPLEMENTARY NOTES

14. ABSTRACT
Specific aim: The specific aim of this project is to assess the effectiveness of a high intensity progressive resistance exercise training program targeting the lumbar extensors to improve lumbar extensor muscular strength and endurance (the desired physiological responses) in US Army Soldiers. Hypothesis: A high intensity progressive resistance exercise for the lumbar extensors will result in a 25% increase in lumbar extensor muscular strength and endurance compared with control following the 12-week intervention. Design: A mixed methods, two-arm, controlled clinical trial with cluster randomization will be conducted. The sampling frame will be soldiers training to become combat medics from 12 platoons, within 3 companies of one domestic US Army base (Fort Sam Houston, TX). Soldiers (n = 592 from 12 platoons) will be randomly assigned (by platoon) to one of two interventions - experimental (n = 296 soldiers from 6 platoons) or control (n = 296 soldiers from 6 platoons). All participants at a given platoon will receive the same intervention and all interventions will be carried out at the US Army base, in addition to the soldiers' usual physical fitness training program. Participants randomized to the experimental group will perform lumbar extensor muscle progressive resistance exercise using standardized protocols. Exercise training will consist of 1 set of high intensity, progressive resistance exercise for lumbar extensors on specialized equipment. Participants in the control group will perform 5 minutes of low intensity core stabilization exercises on the floor. Interventions will be carried out 1X/week for 12 weeks. Outcome measures that will be utilized to test the hypothesis include validated physical fitness tests for lumbar extension muscular strength and endurance. Fitness tests will be conducted at baseline and following the 12-week intervention period.

15. SUBJECT TERMS
musculoskeletal disorders, low back injury; physical fitness, exercise, risk factors

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Table of Contents

Page

INTRODUCTION

Specific aim: The specific aim of this project is to assess the effectiveness of a high intensity progressive resistance exercise training program targeting the lumbar extensors to improve lumbar extensor muscular strength and endurance (the desired physiological responses) in US Army Soldiers.

Hypothesis: A high intensity progressive resistance exercise for the lumbar extensors will result in a 25% increase in lumbar extensor muscular strength and endurance compared with control following the 12-week intervention.

Design: A mixed methods, two-arm, controlled clinical trial with cluster randomization will be conducted. The sampling frame will be soldiers training to become combat medics from 12 platoons, within 3 companies of one domestic US Army base (Fort Sam Houston, TX). Soldiers (n = 592 from 12 platoons) will be randomly assigned (by platoon) to one of two interventions - experimental (n = 296 soldiers from 6 platoons) or control (n = 296 soldiers from 6 platoons). All participants at a given platoon will receive the same intervention and all interventions will be carried out at the US Army base, in addition to the soldiers' usual physical fitness training program. Participants randomized to the experimental group will perform lumbar extensor muscle progressive resistance exercise using standardized protocols. Exercise training will consist of 1 set of high intensity, progressive resistance exercise for lumbar extensors on specialized equipment. Participants in the control group will perform 5 minutes of low intensity core stabilization exercises on the floor. Interventions will be carried out 1X/week for 12 weeks. Outcome measures that will be utilized to test the hypothesis include validated physical fitness tests for lumbar extension muscular strength and endurance. Fitness tests will be conducted at baseline and following the 12-week intervention period.

BODY

The research accomplishments associated with the tasks outlined in the approved Statement of Work (SOW) are described in this section.

A. Pre-Study Procedures (months 1-9)
Task A.1. Complete pre-enrollment regulatory and human subjects protection assurances.
A.1.a. Prepare and submit Institutional Review Board (IRB) applications.
IRB application 1: USF IRB
IRB application 2: Brooke Army Medical Center IRB, AMEDD C&S
Milestone 1: IRB approvals - obtained (month 2)

A.1.b. Prepare and submit DOD human subjects and regulatory documents.
Milestone 2: DOD regulatory approval - obtained (month 6)

Task A.2. Implement facilities and train staff.
A.2.a. Conduct strategic meetings with battalion officers and non-commissioned officer (NCO) cadre.
A.2.b. Prepare exercise facilities.
A.2.c. Train study personnel.

Milestone 3: Site, facilities, personnel - established (month 9)

Accomplishments - SOW section A:
All tasks in the SOW section A have been successfully completed.

B. Specific Aim 1 (months 10-18): In a controlled clinical trial, assess the effectiveness of a progressive resistance exercise training program to improve lumbar extensor muscle strength and endurance in US Army Soldiers from the 232nd Medical Battalion at Fort Sam Houston, TX training to become combat medics.

Task B.1. Carry out recruitment, consent, enrollment, and screening, and baseline assessment procedures.

B.1.a.1. Recruit subjects.
B.1.a.2. Consent and enroll subjects.

Milestone 4: Recruitment, consenting, and enrollment - completed (month 15)

B.1.a.3. Conduct screening procedures.
B.1.a.4. Conduct baseline fitness tests assessing lumbar muscle strength and endurance.

Milestone 5: Screening and baseline fitness tests - completed (month 15)

Task B.2. Administer interventions in experimental and control groups.
Administer interventions for experimental (n = 296 soldiers, 3 companies, 6 platoons) and control groups (n = 296; 3 companies; 6 platoons)
Randomized by platoon: within each company - 2 platoons randomized to experimental and 2 platoons randomized to control.
Experimental group: high intensity progressive resistance exercise for lumbar extensors
Control group: low intensity core stability exercise
Intervention: 1X/week, 12 weeks

Task B.3. Conduct post-training fitness tests assessing lumbar muscle strength and endurance.

Milestone 6: Exercise training and post-training fitness tests - completed (month 18)

Accomplishments - SOW section B:
Recruitment and data collection were initiated in June 2012. Current enrollment figures are as follows:

- Companies enrolled: 3
- Platoons enrolled: 6
- Subjects consented: 312
- Subjects consented who were excluded at screening (e.g. screen failure due to orthopaedic contraindications to resistance exercise) or did not otherwise complete baseline tests (e.g. scheduling issues or did not show up): 57
- Subjects enrolled and randomized (by platoon): 255
    - Core exercise: 131 (3 platoons)
    - Lumbar strengthening exercise: 124 (3 platoons)

Exercise interventions: Exercise interventions have been initiated in approximately 250 subjects from 6 platoons in 3 companies (2 platoons per company). Approximately 5 subjects withdrew after randomization and before initiating exercise training. Subjects from company Delta, the

first company that started the intervention, have completed the intervention period. Overall compliance to the exercise program for company Delta, particularly in the lumbar strengthening group, was lower than expected. The research team has identified issues and implemented a corrective course of action, which has appeared to reduce these compliance issues in the currently enrolled subjects in companies Bravo and Charlie, and for future subjects.

End-of-trial tests: Of the 64 subjects who completed baseline tests and randomized from company Delta (the only company in which study interventions have been completed), 37 subjects completed end-of-trial tests. As previously mentioned, overall compliance for company Delta was lower than expected. The research team has identified issues and implemented a corrective course of action, which has appeared to reduce these compliance issues in the currently enrolled subjects in companies Bravo and Charlie, and for future subjects. We do not no plan to conduct interim analysis on the primary efficacy variables. This analysis of the primary efficacy variables will be conducted when all end-of-trial tests are completed for all subjects.

Safety: No occurrences of definitely related or possibly related serious adverse events have been reported. Definitely related or possibly related minor adverse events or expected side effects (for example, muscle soreness) have occurred at the expected frequency and severity. These adverse events were minor, temporary, and self-limiting, and did not affect physical function or active duty status.

Confidentiality: No known breaches in confidentially have occurred.

IRB regulatory status: BAMC IRB provided annual continuing review and approved the continuation of the study on October 1, 2012.

Potential obstacles that may preclude completing all tasks defined in the statement of work: Assuming the usual operational flow of the target population (32D Medical Brigade) remains intact as it has been since study inception, we do not foresee any serious obstacles that may impede completion of all tasks defined in the statement of work by the end of the study period.

C. Data Analysis and Dissemination (months 19-24)
Task C.1. Analyze data.
Task C.2. Prepare and disseminate final reports, manuscripts, and presentations.

Milestone 7: All study procedures - completed (month 24)

Accomplishments - SOW section C:
Not applicable. Data collection is in progress and no efficacy analyses have been conducted.

KEY RESEARCH ACCOMPLISHMENTS

- All pre-study affairs, such as regulatory and IRB approvals have been obtained and updated.
- Recruitment, enrollment, and baseline tests have been completed in 255 subjects from 6 platoons within 3 companies.
- Exercise interventions have been initiated in subjects from 6 platoons within 3 companies, and completed in subjects from 2 platoons within 1 company.
- End-of-trial tests have been completed in 37 subjects from 2 platoons within 1 company.

REPORTABLE OUTCOMES

Not applicable - Data collection is in progress. Therefore, analyses have not been conducted with the primary efficacy variable, and scholarly products have been not been pursued.

CONCLUSION

The study has been successfully initiated. All pre-study affairs, such as regulatory and IRB approvals have been obtained and updated. Recruitment, enrollment, and baseline tests have been completed in 255 subjects from 6 platoons within 3 companies. Exercise interventions have been initiated in subjects from 6 platoons within 3 companies, and completed in subjects from 2 platoons within 1 company. End-of-trial tests have been completed in 37 subjects from 2 platoons within 1 company. Assuming the usual operational flow of the target population (32D Medical Brigade) remains intact as it has been since study inception, we do not foresee any serious obstacles that may impede completion of all tasks defined in the statement of work by the end of the study period.

REFERENCES

See approved study protocol.

APPENDICES

None.